



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT - 3 2000

5951 '00 OCT -6 A7:56

Lynn Switzer
Director of Regulatory and Clinical
Medtronic Neurological
800 53rd Avenue, NE
Minneapolis, MN 55421

Re: Docket Nos. 00P-0788 and 00D-1455

Dear Ms. Switzer,

This is in response to your letters dated September 25, 2000 to Dr. Russell Pagano of our Office of Device Evaluation. In one letter, you request a 60-day extension to the public comment period concerning the reclassification of the totally implanted spinal cord stimulator (Docket No. 00P-0788). In the other letter, you request a 90-day extension for the public comment period on the guidance document for the totally implanted spinal cord stimulator (Docket No. 00D-1455) after the final order is published. Both comment periods were scheduled to expire October 6, 2000. For the reasons discussed below, FDA is extending both comment periods by 4 weeks to November 3, 2000.

With respect to the notice of panel recommendation on the reclassification petition for the totally implanted spinal cord stimulator, we note that the panel recommendation was made at an open meeting of the panel on September 16 and 17, 1999. Therefore, you have had more than a year to consider your objections to the panel recommendation. On January 31, 2000, you submitted a detailed letter to FDA objecting to the panel recommendation. Also, on July 27, 2000, you made a presentation to FDA about your objections to the reclassification. Therefore, we believe that you have had adequate time to review and respond to the panel recommendation and that an extension of the comment period to November 3, 2000 is sufficient.

With respect to the guidance document, we note that you may submit comments at any time on a guidance document, even after it is finalized. FDA will consider any comments received after the guidance is finalized to determine whether to revise the guidance. We also note that a guidance document is not binding on FDA or the public. Therefore, we also believe that an extension of the comment period to November 3, 2000 is sufficient.

00D-1455

00P-0788

ANSI



If you have any questions about this response, please contact Joseph M. Sheehan of our Regulations Staff at (301) 827-2974.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health